TITLE

PERCUTANEOUS BONE ANCHORED TRANSFERRING DEVICE

DESCRIPTION

Technical field

There is a great need for transferring electrical information and/or electric energy to an inner subcutaneous permanently implanted unit at several medical-technical applications.

The present invention relates to a percutaneous bone anchored transferring device, preferably by means of which an outer electrical unit can be connected to an inner implanted subcutaneous unit.

Varieties of such connecting devices are not unknown, but the present invention differs, i.a. in that the bone anchored and skin penetrating transferring device can be connected in a simple way, beneath the outer limiting surface of the bone, to and from the implanted set of cables/joining device, which transfers electrical information and/or energy, drug, etc., to the inner implanted unit. Furthermore, the new transferring device is designed in such a way that the dimensions are small and that the biocompatibility properties become good.

The primary application described in the description is an electrical connection device which is designed for daily use, i.a., in that the connection becomes simple and in such a way that substantially free rotational positioning is allowed, and that the connection is easily maintained and that details being worn out simply can be exchanged. The connection is furthermore designed in such a way that it disconnects due to an outer mechanical influence being large enough.

Background of the invention and prior art

In spite of an increasing need for a percutaneous connecting device for permanent use, in particular for the transfer of electrical information and/or electric energy there is no commercially available unit being allowed for clinical use (as far as the inventor is aware of in December 1997). This, in spite of the fact that there are several patents within the field.

As a conclusion, it can be said that the reason that these patents have so far not lead to any commercial product is probably due to the fact that the patents describe connecting devices which are either too complicated in that they contains too many poles and ingoing components or that they do not attend to all the nuanced demands raised from a biocompatibility, anatomical, surgical, electric, patient safety and handling points of view on a permanent, percutaneous, electric connecting device for daily use . In the following some relevant published patents concerning electrical connecting devices are commented in particular with regard to differences to the present invention as described.

In US-A-5,562,670 to Brånemark an electrical connecting device is described which is applied by means of a threaded tubular implant where its inwardly turned end has a central bore. Contact means and set of cables are introduced and fixed from the outside of the implant. This is a patent by the pioneer and the inventor to the world comprising industrial business of titan implants of today concerning dental rehabilitation, bone anchored hearing aids, and face prosthesis, knee and finger joints etc, professor P-I Brånemark. Without his basic research activities around biomaterial research in general, and titan implants in particular a long row of new applications/inventions had not seen the light. When it comes to practical realization of the electric connecting device described in US-A-5,562,670 there is a weakness in that the implanted set of cables and the inner implanted unit have to be so small that it can pass through the central bore of the implant. In most applications, however, the inner implant is to large to be able to pass in through the central bore of the implant. In these cases the units have be surgically implanted as an integrated unit or become mounted together with the implant in place or become connected by means of a further implanted and connecting device being small enough. If the contact means should be repaired or maintained, which is necessary with regard to the environment as a skin related implant is subject to (contact surfaces become oxidized etc.), this has to be done in the tube in the patient. If one should wish to remove/exchange the connecting device the whole implanted set of cables has to be removed. Fixation of the implant using threads means that the bone anchored part of the implant has to have a diameter large enough to encompass even the thread as such which clearly restricts the possibilities to encompass connecting details therein, as well. It is desired to encompass the connecting details in the bone anchored part

of the transferring device to reduce the total height of the transferring device. A well functioning transferring device should not extend outside the skin level more than 1 to 3 mm in order to avoid damages from optional outer mechanical violence and in order that the implant should be experienced as acceptable from an aesthetical point of view. Furthermore, a screw implant has to be rotated at the application which means that an asymmetrical design of the implant is very hard to realize. An asymmetric design of the implant is a desire as the bone thickness where the implant, from a practical point of view has be placed, is so thin that the set of cables, as a rule, has to leave the implant in a radial direction. Furthermore, the inner implanted unit has to rotate together at the application if it has been premounted and passes through the transferring device (due to the fact that it is to large to be applied afterwards through the bore), which will lead to practical problems, as well.

US-A-3,870,832 to Fredricson discloses a connecting device for the application of a microphone, which device corresponds, in principle, with the Brånemark patent. Fredricson shows that the retention of the microphone element is done using a locking nut which is applied using an outwardly turned thread on the implant, which should lead to a potential risk for bacterial accumulation and risk for skin irritation. Besides, the construction according to this patent, is characterized by the same weaknesses as described above with reference to patent 5,562,670.

US-A-5,604,976 to Stobie et al discloses a connecting device for a great number of conductors, the inner connecting device of which is not intended to be lowered beneath the surface of the outer limiting surface of the bone, but become fixed above the same but below the soft tissue. In this connecting device the set of cables is lead to the inner implanted unit on the top of the bone beneath the soft tissue. Problems reported in clinical tests using such an arrangement shows that the set of cables having a realistic dimension (minimum 1 to 2 mm in diameter) and being a little elastic creates biocompatibility problem at the skin penetration, probably due to the occurrence of small movements between skin and bone with a foreign material there between. Furthermore, the necessary skin reduction can be jeopardized if the set of cables has not got a very small diameter. The connection can be severed apart by means of tools to loosen a screw connection and can not, for any reason,

be disconnected in daily use. This connecting technique further means that rotation of the outer connecting part is not possible and that an overloading protection from outer influence is missing.

US-A-5,507,303 to Kuzma discloses a connecting device where the implant, for sure, is anchored to the scull bone but where the skin/bone connecting tissue closest to the implant is separated from the scull bone using a large flange. A long experience from skin penetrating titan implants in the scull bone shows that it is of utmost importance that the skin around the penetration area has passed an adequate skin reduction and that the thickness reduced skin is allowed to grow against bone connecting tissue and scull bone (Tjellström, Anders, et al, The Bone Anchored Hearing Aid - design principles, indications and long-term clinical results, Otolaryngologic Clinics of North America, vol 28(1), 1995, pp 53-72). The flange of the actual connecting device hinders the skin to grow to the bone/bone connecting tissue, and the frequency of skin complications can be expected to be relatively high. Furthermore, the whole connecting device is placed outside both bone and skin, which means that its extending part above the skin surface becomes considerable. The retention between the connecting parts is done using magnetic force.

US-A-4,025,964 to Owens discloses a connecting device which unlike the connecting devices above is not anchored to the bone in a stable way. Even small movements of the implant relative to the skin will lead to a great risk for skin irritation. Fixation between the male and female parts of the connecting device is carried out using magnetic attraction force and the parts can not be rotated relative to each other.

US-A-3,995,644 to Parsons discloses a connecting device, as well, which is merely fixed to the skin, and intended to transfer an electrical signal, preferably for electrical stimulation of muscle units. Due to the fact that even small movements between skin and implant create irritation, this type of connecting devices should only be used temporarily and time restricted use.

Finally, there are a number of connecting devices which are intended to be used totally

subcutaneously, such as US-A-4,495,917 to Byers, but these are so different to the present invention concerning functional requirements and constructive solutions that a further analysis does not seem to be meaningful.

US-A-4,328,813 relates to a system for anchoring a brain cable and is only intended to geometrically fix or lock a cable such as an electrode for the stimulation of a certain point in the brain. The cable is thereby intended to be brought underneath the scalp to an electric stimulator. As the implant is manufactured in an elastic material, and provided with slots, the implant can not be used for a bone anchored percutaneous transferring device.

SE-C-503,790 relates to a passive screw implant for the transfer of vibrations from an outer vibrator (loud speaker) to the scull bone. Such an implant can not transfer electrical signals, energy or drugs to the inner of a body and, has not, when construed, been faced with the problems that the present invention provides a solution to.

The object of the present invention and features of a principle nature.
As mentioned above there is a great demand for, within several medical-technical applications, to transfer electrical information and/or electric energy or to communicate in an other way (e.g. to distribute drugs or to obtain airing of interior cavities and cell systems) from an outer unit to a subcutaneously implanted inner unit. Such subcutaneously implanted units can be hearing technical aids, e.g. coclear implants, middle ear implants, bone transfer implants, device for suppression of tinnitus and other medical-technical aids, e.g. stimulators of different types, registration means for biological signals, pumps for distribution of drugs, evacuation of liquids etc. In principle such devices consist of the following essential parts: outer unit, connecting device, skin penetrating and bone anchored transferring device, set of cables/communication channel, and subcutaneously implanted inner unit. A fundamental device utilizing a connecting device according to the present invention is provided in Figure 13, where the outer unit can e.g. be a hearing apparatus without loud speaker, and the inner unit can be a vibrator for the generation of bone transferred sound. The reason that a set of cables/communication channel between the transferring device and the inner unit is needed is that the bone thickness where the

transferring device from a practical and anatomical point of view has to be placed, is so thin that the inner unit will get no room. On the other hand there is plenty of room a short distance away, and closer to the auditory canal in the part of the temporal bone mentioned processus mastoideus. Where and how the inner unit will be placed is thereby dependent upon the application.

Although, if the present invention concerning a transferring device can be used for other communication of long term stable type, the following describes the primary application where an outer unit can be connected electrically to an inner implanted subcutaneous unit by means of the presently proposed transferring device. Varieties of such connecting devices are not unknown but the present invention is unique for the following reasons:

1. The application/fixation between the bone anchored part and the skin penetrating transferring device and the set of cables takes place below the outer bone level, preferably in the bottom part of the transferring device.

The advantages using this solution is

a. that the set of cables and the implanted inner unit can be assembled, and disassembled, respectively, separately, which is not only essential for facilitating the first installation but in particular at future events, of the type skin irritation/damages/maintenance/updatings, when the bone anchored and skin penetrating transferring device, and the set of cables (optionally including the inner unit), respectively, need to be exchanged, most often independent from each other. Further the transferring device can be removed in such a way that intact skin can be replaced without influencing the set of cables and an inner, implanted unit. In this way all inner vital parts can be retained resting underneath the skin, simultaneously as the skin above the penetration area is replaced for a longer or shorter term period. This way of acting can be of great importance, if the patient should like to temporarily cease the treatment but have the possibility to easily retain the treatment when the need, optionally, reoccurs;

b. that the transferring device and the set of cables (including the inner units connected to the other end thereof) can be rotated independently from each other at the mounting, and

optional dismounting, respectively.

C. that the skin closest to the penetration area can be reduced to the thickness desired, and be allowed to rest/heal to bone tissue and bone connective tissue which facilitates by the fact that the set of cables is drawn beneath and not over the outer bone surface.

2. The transferring device which is lowered into the bone tissue will be anchored by means of radial arms placed outside the outer surface of the bone, and will in turn be fixedly screwed to the bone tissue.

The advantages using this solution are:
that a first contact unit can be placed within the bone anchoring part of the transferring device (beneath the outer bone surface) without its outer diameter becoming undesirably large. This is possible as the bone anchoring part of the transferring device does not contains threads which otherwise take large room. By placing part of the connecting device into the bone anchoring part of the transferring device the part of the transferring device extending outside the skin can become minimal, which is advantageous partly from an aesthetical point of view, partly with regard to the risk for outer mechanical damage of the implant;

3. The connecting device comprises one middle connecting unit placed in the outer part of the transferring device. Hereby two connecting devices occur one outer to be connected to an outer unit, and one inner to be connected to the set of cables.

This solution provides the following advantages:

a. the middle connecting unit which will be exposed to the outer environment is a disposable detail designed to be simple to exchange if there should be bad contact due to the appearance of an oxide layer etc, or if a damage should occur in another way;

b. the middle connecting unit, in combination with a tightening ring, protects the inner and more sensitive connecting device from an outer environmental influence. Furthermore, the

middle connecting unit will serve, in combination with the tightening ring, as a first biological bar against the passage of undesired compounds/bacteria to the tissue inside the transferring device. The main bar in connection herewith, is, however, the screw joint between the connecting means of the transferring device and the set of cables;

c. the outer connecting device can be designed in such a way that it will allow free rotational positioning, will provide for a simple connection/disconnection, and will serve as an overload protection aid.

Experiences from more than 20 years of developing work with bone anchored hearing aids (Håkansson, Bo et al, The Bone Anchored Hearing Aid, Edited by Dan Tolman & P-I Brånemark, to be published) where more than 5000 patients have been operated and been provided with a mechanical bayonet joint (SE-C-8107161-5) show that al aspects mentioned above are of importance to have a connecting device work in clinical use for long time. It might seem that there is a restriction in that the present invention can hardly be realized using more than 4 to 6 poles, maintaining reasonable dimensions. If a larger number of poles is desired, as for example using the coclear implant, wherein up to 20 to 30 electrodes shall become separately provided it is suitable to utilize so called multiplexing. Multiplexing means that the information is transferred sequentially in a signal cable through the percutaneous electrical connection in order to then in an electronic way, become split up in the inner implanted unit and become distributed to the number of electrodes desired. Multiplexing is a well known technique when it is used within all communication (telecommunication and television) where one normally has not admittance to parallel cables. That which further speaks against a great number of poles in percutaneous electrical contact is that complexity and restrictions of both medical and technical character increases dramatically using an increasing number of poles. Generally, in most applications one can manage using three poles which then might be plus, and minus poles, respectively, as well as one signal cable. In specific hearing applications one sometimes wish to drive a push-pull vibrator where two cables are signal lines and one line is voltage feeding.

Short description of the figures

Figure 1 is a compilating cross sectional view of a helping aid where an electrical connecting device of the present invention is utilized.

Figure 2 is a cross sectional view of the present invention comprising a skin penetrating and bone anchored transferring device with its set of cables joined in the bottom part of the transferring device as well as a middle connection unit and tightening ring as mounted. In this embodiment of the middle connecting unit contact metal sheets of the outer contacting means attacks the unit with a radial force.

Figure 3 shows a cross sectional view of the transferring device shown in Figure 2.

Figure 4 shows the embodiment of Figure 3 seen from above.

Figure 5 shows the transferring device according to Fig. 2 to 4 using a connecting means for connection to an inner unit.

Figure 6 shows different details of a middle unit for insertion in the transferring device according to Fig. 2 to 4.

Figure 7 shows an embodiment of how the outer unit is connected to the middle connecting unit.

Figure 8 shows a simple tool for mounting, and dismounting, respectively, the middle connecting unit as well as how contact surfaces can be cleansed/maintained.

Figure 9 shows an alternative embodiment of the middle connecting unit, where the middle connecting unit is fixed by means of slotted radially spring biassed arms.

Figure 10 shows a lid used when the middle connecting unit and its contact surfaces should be protected, for example while taking a bath in salt water, and having a sauna.

Figure 11 shows an embodying example how the invention can be used at the distribution of a drug and evacuation/airing, alternatively, of internal cavities.

Figure 12 shows an alternative design of the contact means where the contact metal sheets of the outer contact means are connected using an axial contact force.

Figure 13 shows a schematic picture of a medical-technical helping aid where a connecting device according to the present invention is brought into place.

Description of the present invention

1 denotes a scull bone with its skin and skin tissue 2, which has been thinned using known surgical technology. An electrical connection 3 manufactured in a tissue compatible material

such as titan, is anchored into the scull bone 1 using screws 4, suitable of the same type of material, attached in said bone, whereby the connecting device is placed in the bone itself by means of a boring and lowering into the drilled hole 5. From the bottom part of the connecting device 3 a set of cables 6 has been drawn to an inner unit, not shown, such as a vibrator acting against the hearing bones.

The connection 3 comprises according to Fig. 2 - 4 a transferring part 11 which comprises a number of arms 12 provided with holes 13 for carrying a screw for anchoring it by means of screws 4. The number of arms can be three, four, five or more depending on the size and intended placing. The arms 12 are pivotable and inclinable to admit maximum of adaptation to the substrate to which they shall be screwed. The transferring part 11 has outwardly a substantially cylindrical form with the exception of the arms 12 as well as an inwardly substantially cylindrical form. In the upper part 14 the transferring part 11 is thinned to allow deformation if a large load should occur on the transferring part 11. On its inside the transferring part 11 of this embodiment has a groove 15 for receiving an O-ring 16. In the bottom part 17 of the transferring part 11 a hole 18 is arranged whereby its outwardly turned limiting surfaces 19 are obliquely arranged. The transferring part 11 is suitably teased in its lower Cylindrical part, the bottom part 17, to allow adaption to the tissue 1 in which it will be introduced. The transferring part 11 is shown as an integrated unit, but can be split and joinable by means of a screw joint over the plane in which the arms 12 are arranged.

In the transferring part 11 of this embodiment a connection means 21 is introduced from beneath and fixedly arranged tom the transferring part 11 by means of a screw joint by means of a locking nut 22. The connection means 21 shows a conical upper limiting surface 23 intended to abut perfectly to the hole 18 and its limiting surfaces 19 of the transferring part 11. In the connection means 21 an electrical connecting unit 24 is arranged the set of cables 6 of which is drawn out through a side opening 25 of the connection means 21.

To the connection means 24 a second connection unit 26 is arranged whereby one unit has male pins or metal sheets nd the other unit shows female pins or metal sheets for obtaining a good electrical connection between the connection units 24 and 26.

The connection unit 26 is in turn introduced into a middle insert 31 around which tree different poles 32 , 33, 34 are arranged and connected via metal sheets and cables to the connection unit 26, which is a unit built by cylindrical parts made of plastic or another non-conducting material. In the centre of the middle insert 31 a contact metal sheet of a plus pole 32 is placed. From this plus pole 32 a connecting line leads to a corresponding plus pole 26p on the connection unit 26. Around upper cylindrical part of the middle insert a contact metal sheet of a signal pole 33 is placed, which , via a not shown through hole, is connected to a corresponding signal pole 26s of the connection unit 26. Further, there is a contact metal sheet of a minus pole 34 arranged around the lower cylindrical part of the middle insert 31, whereby this minus pole 34 is in contact with a corresponding minus pole 26m of the connection unit 26, not shown.

An outer contact 41 is connected to the middle insert 31 with its different contact metal sheets, which contact can be a microphone unit of a hearing aid, another signal treatment unit, or as evident from Fig. 11 be a unit for the distribution of drugs or airing of a cavity. The outer contact 41 comprises a number of pins 42, 43, and 44 which connect to their respective contact metal sheet 32, 33, and 34. The pins 42 abut to the centre contact metal sheet 32 whereby this, at its point, is bent outwardly from the centre to rest against the sheet 32. In the same way the point of the sheet 43 bent outwardly to connect to the sheet 33. The pins 44 are bent inwardly towards the centre to connect to the edge of the contact sheet 34, which edge can be made stepped to allow stepping/variation of the position of the contact house/hearing apparatus from a rotational point of view. Hereby the sheet 34 is bent in an upward direction on two facing points to allow the pins 44 to be brought down beneath the edge of the contact sheet.

The pins 44 have a primary task to retain the outer contact 41 to the middle insert 31. At a load being high enough the pins will, however, pass over the edge to create a security release of the outer contact part visavi the inner middle insert and thereby the whole transferring device.

51 denotes a tool for removal and introduction of the middle insert comprising the

connection units from the transferring device 11. The tool 51 is hereby tubular and slotted in such a way that it by means of the grip 52 can be pressed together to retain a middle insert 31.

In fig. 10 a lid 61 is shown, which can be placed over the middle insert 31 when the outer contact 41 has been removed. It is suitable to apply the lid 61 when visiting a sauna or being in salt water. Hereby the lid 61 contains an upset 62 which snaps down over the upper edge of the transferring device 11.

In fig. 9 an alternative fixation of the middle insert 31 is shown, whereby its upper part is slotted and stretches outwardly, whereby this upper part stretches in beneath the edge of the upper part of the transferring device 11, the upper edge of which is hereby upset. Further, the embodiment shows an alternative arrangement of the O-ring.

In fig. 12 an alternative design of the contact means is shown having an axially elastic contact pin 71 which abuts a circuit card 72 provided with circuit lines.

Fig. 11 shows, as mentioned, an embodiment for the distribution of drugs in the form of a solution whereby an injection needle 81 penetrates a membrane 82 arranged in the middle insert as well as a membrane 83 arranged in the connection means. A tube 84 connects to the injection needle 81 for the addition of a drug solution, as well as a tube from the lower part of the connection means for the distribution at a suitable site in the body. These tubes and the injection needle can be used for the airing of a cavity, as well, such as a middle ear suffering from continuous inflammations.